

REMARKS

This paper is submitted in response to the Office Action dated November 4, 2003 in the above-identified application. The Examiner has rejected Applicants' arguments for examination of the instant application as a single inventive entity comprising the claimed polynucleotides and claimed polypeptides. Thus, Claims 1-20, 22 and 46, as drawn to the elected polypeptide encoded by nucleotides 1-132 of SEQ ID NO:2, are presently pending and subject to examination. In addition, Claims 47-53 have been added to capture subject matter removed from Claims 1, 7 and 11 by the amendments described hereinbelow. No new matter has been added.

The Examiner has noted that, in contrast to Applicants' previous assertions, Hoffman *et al.* (*Immunol. Today* 1992;13:411-415) does in fact read on Claim 1 of the instant application, because, for purposes of searching and applying prior art under 35 U.S.C. § 102 and 103, the phrase "consisting essentially of" will be read broadly to include additional elements unless the specification or the claims provide a clear indication of the basic and novel characteristics of the peptide that would be materially changed by the inclusion of additional elements. *See* MPEP § 2111.03, at p. 2100-50-51. Applicants thank the Examiner for this clarification.

The Examiner has acknowledged Applicants' claim for foreign priority based on French application FR98/04933, filed on April 15, 1998, but notes that a translation of the certified copy of this French application has not been filed with the United States Patent and Trademark Office (USPTO). The failure of the USPTO to accord the instant application priority to April 15, 1998 has resulted in at least one article published after this priority date being cited against the instant application as prior art under 35 U.S.C. § 102 and 103 (See Sections III and IV below). To perfect the priority claim of the instant application, Applicants enclose herein a certified translation of French patent application FR98/04933.

The Examiner has objected to the specification and the claims of the instant application as containing various informalities. In response, Applicants have amended the specification and claims of the instant application as suggested by the Examiner. Applicants contend that the amendments made to overcome these objections do not constitute the addition of new matter. Applicants assert that the specification and claims as presently amended satisfy the requirements of 37 C.F.R. § 1.71 and 1.75, and respectfully request that the Examiner withdraw the objections to the specification and the claims.

The Examiner has rejected Claims 1-20, 22 and 46 under the second paragraph of 35 U.S.C. § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In response to these rejections, discussed in detail in Section II below, Applicants have amended Claims 1, 8, 11, 12, 14, and 19 in accordance with the Examiner's suggestions and to more distinctly and clearly claim the subject matter that the Applicants regard as their invention. Applicants have cancelled Claims 5 and 20. Applicants assert that support for the amendments to the claims presented herein may be found in the specification and claims as originally filed, and thus these amendments do not constitute the addition of new matter. In view of these amendments, Applicants respectfully request that the rejections of Claims 1-20, 22 and 46 under the second paragraph of 35 U.S.C. § 112 be withdrawn, and that the pending claims be allowed to issue.

The Examiner has rejected Claims 1-19 and 46 under 35 U.S.C. § 102(a) as being anticipated by Lamberty *et al.* (*J. Biol. Chem.* 1999;274:9320-9326). In response, Applicants note that Lamberty *et al.* was published on April 2, 1999, which is well after the April 15, 1998 priority date of the instant application. Applicants therefore assert that Lamberty *et al.* does not qualify as prior art under 35 U.S.C. § 102(a). As discussed below (Section III), Applicants have

perfected the priority claim of the instant application. In light of this action, Applicants respectfully request that the rejection of the instant application under 35 U.S.C. § 102(a) be withdrawn.

Claims 1-4, 11 and 15 also have been rejected by the Examiner, under 35 U.S.C. § 102(b), as being anticipated by Charlet *et al.* (*J. Biol. Chem.* 1996;271:21808-21813). Applicants have amended Claim 1 of the instant application to incorporate the limitations of Claim 5, which accordingly has been cancelled. Applicants respectfully submit that the isolated peptide of Claim 1, as presently amended, does not read on the *Leiurus* defensin peptide of Charlet *et al.*, and therefore respectfully request that the rejection of Claims 1-4, 11 and 15 under 35 U.S.C. § 102(b) be withdrawn.

The Examiner has rejected Claims 1-19, 22 and 46 under 35 U.S.C. § 103(a) as being obvious over Lamberty *et al.* (*supra*) in combination with DeRose *et al.* (U.S. Patent No. 6,465,719). Applicants have perfected their priority claim as discussed below (Section III). Applicants maintain that, because this claim of priority to French application FR98/04933, filed on April 15, 1998, has been perfected, neither Lamberty *et al.* nor DeRose *et al.* qualify as prior art under 35 U.S.C. § 102. Removal of these publications as prior art under 35 U.S.C. § 102 also precludes their application under 35 U.S.C. § 103(a). Therefore, Applicants respectfully request that the rejection of Claims 1-19, 22 and 46 under 35 U.S.C. § 103(a) be withdrawn.

Applicants respectfully request reconsideration of the above-identified application in light of the amendments and remarks presented in the instant Amendment.

**I. The Specification and Claims Are in Compliance 37 C.F.R. §§ 1.71 and 1.75**

The Examiner has objected to the specification and the claims of the instant application as containing various informalities. Specifically, the Examiner has objected to the presence of

the abbreviations "HIV" (page 1, line 27), "PR-1 $\alpha$ " (page 9, line 11), and "HPLC" (page 18, line 3) without their definitions being provided at their first instance of use. The Examiner also objects to the use of "SEQ ID NO 2," requiring instead substitution of the phrase "SEQ ID NO:2" throughout the specification. Substitution of "°C" for "·C" throughout the specification is also suggested. Clarification of the phrase "HPIC<sub>18</sub>" on page 32, line 19 is requested. The Examiner also requests the replacement of the phrases "preferably 10," "preferably 9," and "preferably 7," in Claim 1 by the phrases "preferably 10 amino acid residues," "preferably 9 amino acid residues," and "preferably 7 amino acid residues," respectively.

In response, Applicants have amended the specification of the instant application as suggested by the Examiner. Due to the global nature of the requested changes to the specification, Applicants supply herein a substitute specification in accordance with 37 C.F.R. §§ 1.121 and 1.125. Applicants state that this substitute specification contains no new matter.

Applicants also have amended Claims 1, 7 and 11 in response to the Examiner's objection regarding the terminology used to claim the preferred embodiments of general formula I, as well as to further define their invention. New claims 47-53 have been added to specifically claim the deleted subject matter originally present in Claims 1, 7 and 11. Applicants contend that support for these new claims may be found in Claims 1, 7 and 11 as originally filed.

## **II. The Claims Are Definite**

Claims 1-20, 22 and 46 have been rejected under the second paragraph of 35 U.S.C. § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner contends that Claim 1 is indefinite in the recitation "peptide residue," which the Examiner contends is not defined in the

specification. The Examiner also asserts that Claim 11 is unclear as to the representation of the term "Xag" and the phrase "a variable residue having a sequence...."

Claim 12 is allegedly indefinite because it is unclear whether a hydroxyl group is being claimed in place of the C-terminal carboxyl group of the threonine residue. Claim 14 is allegedly indefinite in that the term "targeting" is unclear. Claim 19 is deemed indefinite because it does not clearly indicate that the recited signal peptide is encoded by the PR-1 $\alpha$  gene.

Claim 22 is said to be unclear because the term "vehicle" is allegedly not defined in the specification. Claim 22 is also allegedly indefinite because it ostensibly is directed to polypeptides encoded by non-elected nucleotide sequences of SEQ ID NOS:1, 3 and 18, rather than the elected polypeptide encoded by nucleotides 1-132 of SEQ ID NO:2. Applicants believe that this latter rejection is more appropriately applied to Claim 20.

In response, Applicants have amended Claims 1, 8, 11, 12, 14, 15, and 19, and have cancelled Claim 20. Claims 1, 8 and 11 have been amended to more clearly define the variable terms present in these claims as representing variable numbers of amino acid residues rather than a peptide residue of amino acids. Support for these amendments is provided by the corresponding claims as originally filed. Applicants assert that these amendments do not constitute the introduction of new matter.

Claims 1, 11 and 12 have been amended to more clearly denote that the terms "NH<sub>2</sub>" and "OH" were intended to refer to the N-terminal amino and C-terminal carboxyl moieties, respectively, of the peptides recited in these claims. Applicants assert that one of ordinary skill in the art, when reading the claims as originally written, would understand this meaning of these phrases. Thus, Applicants contend that the corresponding originally-filed claims provide the

necessary support for these amendments. Applicants therefore assert that these amendments do not constitute the introduction of new matter.

Applicants have amended Claim 14 to indicate that the term "targeting" of a peptide in the original claim referred to the extracellular or subcellular localization of the peptide within a host organism. Support for this amendment may be found, *inter alia*, at paragraph [0027] on page 6 of the substitute specification included herein.

Claim 15 has been amended to bring consistency to the usage of the term "disulfide" within the claims.

Claim 19 has been amended to indicate that the signal peptides to be included in the claimed fusion peptide are those encoded by the tobacco PR-1 $\alpha$  or maize polygalacturonase PG1 genes, or that present at the N-terminal of the precursor of factor Mat alpha 1. Support for these amendments may be found, *inter alia*, in paragraphs [0030] to [0034] on pages 7-8 of the substitute specification included herein.

Claim 20 has been cancelled.

Applicants have not amended Claim 22 in response to the Examiner's rejection because a careful review of the specification reveals that the term "vehicle" is adequately defined in the specification at, *inter alia*, in paragraph [0037] on pages 8-9 of the substitute specification included herein.

In light of these amendments and arguments, Applicants respectfully request withdrawal of the rejection of Claims 1-20, 22 and 46 under the second paragraph of 35 U.S.C. § 112 and permit the issuance of the pending claims as presently amended.

**III. The Claims Are Not Anticipated**

The Examiner has rejected Claims 1-19 and 46 under 35 U.S.C. § 102(a) as being anticipated by Lamberty *et al.* (*J. Biol. Chem.* 1999;274:9320-9326). Claims 1-4, 11 and 15 also have been rejected by the Examiner, under 35 U.S.C. § 102(b), as being anticipated by Charlet *et al.* (*J. Biol. Chem.* 1996;271:21808-21813).

In response, Applicants first note that while acknowledgement has been made by the Examiner of Applicants' claim for foreign priority based on French application FR98/04933, filed on April 15, 1998, Applicants apparently have not been credited with this priority date. This failure to recognize the priority claim of the instant application to French application FR98/04933 appears to result from the fact that the United States Patent and Trademark Office has not received an English translation of FR98/04933, a certified copy of which was received by the International Bureau of WIPO on April 27, 1999 (see enclosed Form PCT/IB/304). Applicants enclose herein a certified translation of French patent application FR98/04933. Applicants assert that this submission is sufficient to perfect the priority claim of the instant application. In light of Applicant's entitlement to a priority date of April 15, 1998, Applicants assert that Lamberty *et al.*, which was published on April 2, 1999, does not qualify as prior art under 35 U.S.C. § 102(a). Applicants therefore respectfully request that the rejection of the instant application under 35 U.S.C. § 102(a) be withdrawn.

Regarding the rejection under 35 U.S.C. § 102(b) in view of Charlet *et al.*, Applicants herein amend Claim 1 to indicate that the "Xad" moiety of the isolated peptide comprising the peptide sequence of formula (I) represents the peptide sequence -Lys-Xad'-Xad"-Gly-His- (SEQ ID NO:40), in which Xad' represents a peptide residue of 1 basic amino acid and Xad" represents a peptide residue comprising from 0 to 5 amino acids. Support for this amendment may be found

in the specification, *inter alia*, on **page 5, lines 10-13**, and in the original Claim 5, on page 68, lines 7-12. Applicants assert that this amendment therefore does not constitute the introduction of new matter. Applicants respectfully submit that the isolated peptide of Claim 1, as presently amended, does not read on the *Leiurus* defensin peptide of Charlet *et al.* In light of this amendment, Applicants respectfully request that the rejection of Claims 1-19 and 46 under 35 U.S.C. § 102(b) be withdrawn.

#### IV. The Claims Are Not Obvious

Claims 1-19, 22 and 46 have been rejected under 35 U.S.C. § 103(a) as being obvious over Lamberty *et al.* (*J. Biol. Chem.* 1999;274:9320-9326) in combination with DeRose *et al.* (U.S. Patent No. 6,465,719). According to the Examiner, Lamberty *et al.* teach an antimicrobial peptide, heliomicine, comprising six cysteine residues and having the structural characteristics set forth in formula I of Claim 1. DeRose *et al.* allegedly teach a peptide sequence of drosomycin, which the Examiner contends reads on formula I of Claim 1.

In response, Applicants reiterate their assertion that Lamberty *et al.*, which was published on April 2, 1999, does not qualify as prior art against the instant application because the perfected April 15, 1998 priority date of the instant application precedes the April 2, 1999 publication date of Lamberty *et al.*. Thus, Lamberty *et al.* cannot be used as the basis of an obviousness rejection of the instant application.

With regard to DeRose *et al.*, Applicants also note that this issued U.S. patent was filed on January 11, 2000, which is after the perfected April 15, 1998 priority date of the instant application. Thus, this U.S. patent does not qualify as Section 102(e) prior art and cannot be used as the basis of an obviousness rejection against the instant application. In light of the



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perfection of the priority claim of the instant application, Applicants respectfully request that the rejection of the pending claims under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

Applicants maintain that in view of the amendments and remarks made herein, the claims are in condition for allowance. A Notice of Allowance is earnestly solicited.

Applicants believe that no fees are due with this timely-filed response. However, should any fees be required in connection with this response, the Commissioner is hereby authorized to charge any required fees to Deposit Account Number 02-4377. A duplicate copy of this communication is enclosed.

Respectfully submitted,

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Enclosures